UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 22, 2024

Autolus Therapeutics plc
(Exact name of registrant as specified in its Charter)

England and Wales	**001-38547**	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

The Mediaworks
191 Wood Lane
London W12 7FP
United Kingdom
(Address of principal executive offices)(Zip Code)

(44) 20 3829 6230
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, par value $0.000042 per share	AUTL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

On January 22, 2024, Autolus Therapeutics plc issued a press release announcing the U.S. Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) for obecabtagene autoleucel (obe-cel) for patients with relapsed/refractory (r/r) Adult B-Cell Acute Lymphoblastic Leukemia (ALL). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of November 16, 2024, a standard review timeline consistent with recently approved CAR T therapies.

The information contained in the presentation is furnished as Exhibit 99.1 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits

d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press release dated January 22, 2024

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AUTOLUS THERAPEUTICS PLC

Dated: January 26, 2024

By: /s/Christian Itin

Name: Christian Itin

Title: Chief Executive Officer

Exhibit 99.1

Autolus Therapeutics announces acceptance of Biologics License Application for obecabtagene autoleucel (obe-cel) as a potential treatment for relapsed/refractory Adult B-cell Acute Lymphoblastic Leukemia (ALL)

January 22, 2024 at 7:00 AM EST

- PDUFA Goal date is November 16, 2024
- Company on track to submit a marketing authorization application to the European Medicines Agency (EMA) in the first half of 2024

LONDON, Jan. 22, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces that the U.S. Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) for obecabtagene autoleucel (obe-cel) for patients with relapsed/refractory (r/r) Adult B-Cell Acute Lymphoblastic Leukemia (ALL). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of November 16, 2024, a standard review timeline consistent with recently approved CAR T therapies. The FDA is not currently planning to hold an advisory committee meeting to discuss this application.

The BLA submission is based on data from the Pivotal Phase 2 FELIX study of obe-cel in adult r/r B-ALL. The data were presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2023, with updated data presented at the Annual Meeting of the American Society for Hematology Meeting (ASH) in December 2023.

“Acceptance of the BLA filing is an important milestone for Autolus and we look forward to continuing our collaboration with the FDA during the review cycle,” commented Dr. Christian Itin, Chief Executive Officer of Autolus. “With the PDUFA date set for November, we remain focused on preparing for the potential launch of obe-cel.”

Autolus plans to submit a Marketing Authorization Application for obe-cel in relapsed/refractory ALL to the European Medicines Agency (EMA) in the first half of 2024.

Obe-cel has been granted Orphan Drug Designation by the FDA, Orphan Medical Product Designation by the EMA, Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA and PRIority MEdicines (PRIME) designation by the EMA for adult r/r B-ALL.

About Autolus Therapeutics plc

Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer and autoimmune disease. Using a broad suite of proprietary and modular T cell programming technologies, the Company is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize target cells, break down their defense mechanisms and eliminate these cells. Autolus has a pipeline of product candidates in development for the treatment of hematological malignancies, solid tumors and autoimmune diseases. For more information, please visit www.autolus.com.

About obe-cel (AUTO1)

Obe-cel is a CD19 CAR T cell investigational therapy designed to overcome the limitations in clinical activity and safety compared to current CD19 CAR T cell therapies. Obe-cel is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. Clinical trials of obe-cel have demonstrated that this “fast off-rate” profile reduces toxicity and T cell exhaustion, resulting in improved persistence and leading to high levels of durable remissions in r/r Adult ALL patients. The results of the FELIX trial, a pivotal trial for adult ALL, are being prepared for regulatory submissions with the FDA and EMA. Autolus is conducting a Phase 1b study in paediatric patients with ALL and aggressive B-NHL and iIn collaboration with UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL.

About obe-cel FELIX clinical trial

Autolus’ Phase Ib/II clinical trial of obe-cel enrolled adult patients with relapsed / refractory B-precursor ALL. The trial had a Phase Ib component prior to proceeding to the single arm, Phase II clinical trial. The primary endpoint is overall response rate, and the secondary endpoints include duration of response, MRD negative CR rate and safety. The trial enrolled over 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom and Europe. [NCT04404660]

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding the Company’s anticipated transition plans and timing from a clinical to commercial stage company. Any forward-looking statements are based on management’s current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, but are not limited to, the risks that Autolus’ preclinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; the results of early clinical trials are not always being predictive of future results; the cost, timing, and results of clinical trials; that many product candidates do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; and possible safety and efficacy concerns. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Autolus’ actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Autolus' Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 7, 2023, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the Securities and

Exchange Commission. All information in this press release is as of the date of the release, and Autolus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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